Nos. 10-453

IN THE

Supreme Court of the United States

APOTEX, INC.,

Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, *ET AL.*,

Respondents.

On Petition for Writ of Certiorari to the U.S. Court of Appeals for the D.C. Circuit

BRIEF IN OPPOSITION OF RESPONDENT TEVA PHARMACEUTICALS USA, INC.

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QUESTION PRESENTED

Whether the D.C. Circuit erred in holding that the district court did not abuse its discretion by denying Petitioner's motion for preliminary injunctive relief.

PARTIES TO THE PROCEEDING

Petitioner Apotex, Inc. was the plaintiff-appellant below.

Respondents Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services; Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs; the U.S. Food and Drug Administration; and the U.S. Department of Health and Human Services were the defendants-appellees below.

Respondent Teva Pharmaceuticals USA, Inc. was an intervenor-defendant/appellee below.

Non-party Roxane Laboratories, Inc. was a plaintiff-appellant below and thus is a respondent under this Court's Rule 12.6.

CORPORATE DISCLOSURE STATEMENT

Respondent Teva Pharmaceuticals USA, Inc. ("Teva") is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. through the following parent companies: (i) Orvet UK Unlimited (Majority Shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; and (ii) Teva Pharmaceutical Holdings Cooperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva. Teva Pharmaceutical Industries Ltd. is the only publicly traded direct or indirect parent company of Teva, and no other publicly-traded company owns more than 10% of its stock.

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INTRODUCTION

Respondent Teva Pharmaceuticals USA, Inc. ("Teva") began selling generic losartan potassium products on the evening of April 6, and its 180-day period of marketing exclusivity for those products thus ended at the stroke of midnight on October 3—the day *before* Apotex, Inc. ("Apotex") filed its Petition challenging Teva's then-expired exclusivity period. Accordingly, this case was moot on arrival, and the Petition should be denied. Nothing this Court can say or do would revive Apotex's lone claim, which sought only declaratory and injunctive relief that would have allowed the company to launch its losartan potassium products *before* the scheduled expiration of Teva's now-concluded exclusivity period. Needless to say, this Court is not in the business of exercising its discretionary jurisdiction to render advisory opinions on purely academic matters, and it should not do so here.

This case would in any event be a spectacularly poor vehicle for doing so, because it bears the dubious distinction of attempting to raise a *moot* question in an *interlocutory* posture. After all, no final judgment has been entered below. The district court merely denied Apotex's motion to preliminarily enjoin Teva from marketing its products, and the D.C. Circuit's opinion simply affirmed that discretionary decision before remanding the case. Pet. App. 3a.

While Apotex nonetheless pretends that the merits of its claim are before the Court, *see* Pet. at i, that simply isn't so. The preliminary injunction calculus turns not only on whether the movant has shown a likelihood of success, but also requires proof

that the movant is "likely" to suffer irreparable harm in the absence of interim relief. *Winter v. NRDC, Inc.*, 129 S.Ct. 365, 375-76 (2008). Apotex, however, does not challenge the district court's factual finding that it would not have suffered an irreparable harm from the denial of injunctive relief—and, given that Teva's exclusivity period has come and gone, Apotex cannot possibly make that showing now. There is thus no basis for reaching the merits. The D.C. Circuit's decision to affirm the district court's denial of Apotex's preliminary injunction motion could be summarily affirmed based solely on the equities, leaving any discussion of the merits for an appeal in which the legal issues are presented squarely (and actually matter).

And while the fact that Apotex's requests for preliminary and permanent injunctive relief *both* are moot seemingly would leave the district court with little left to do on remand, Apotex apparently doesn't think so. When the district court recently issued an order to show cause why judgment should not be entered in favor of FDA (and Teva), Apotex opposed the entry of final judgment; indeed, it would not even commit to dismissing its lawsuit in the event this Court denies *certiorari*. Resp. App. 8a.

Even if there were no jurisdictional or procedural impediment to this Court's review, and even if the merits were squarely presented, there still would be no need for the Court to intervene. In short, there is no division of authority on the single question presented by the Petition. Two different panels of the D.C. Circuit now have rejected Apotex's arguments, in decisions that are fully consistent with that of a third D.C. Circuit panel that rejected

Apotex's arguments under the prior version of the statute, *see Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). Suffice it to say, no other court has weighed in on the other side (whether under this version of the statute or its predecessor).

Apotex tries to downplay the courts' consistent rejection of its arguments by speculating that a circuit split is unlikely to develop because most Hatch-Waxman cases are filed in the District of Columbia. But there is no reason why that must be so: Unlike many federal agencies whose decisions are subject to exclusive review in the D.C. Circuit, FDA can be—and often is—sued in other jurisdictions. That likely explains why the Agency's senior Hatch-Waxman counsel reportedly told a recent conference that the issues implicated by this litigation are "likely to arise again soon *in other courts*." David Belian, *FDA Expects More Litigation Over Generic Exclusivity*, GENERIC LINE, Oct. 27, 2010 (Resp. App. 11a) (emphasis added).

Finally, and perhaps most important, the D.C. Circuit's analysis was correct. Contrary to Apotex's assertion that the appellate court "gave no meaningful consideration to th[e statute's] text," Pet. 29, that's precisely what the D.C. Circuit did. In fact, Apotex's real complaint is not that the D.C. Circuit failed to consider the statutory text; it is that the appellate court considered *the whole text* of the statute and not just the snippets Apotex focuses on. Indeed, as Judge Williams carefully explained in the precursor to the decision at issue here, Apotex's proposed interpretation of the statute's forfeiture triggers is both inconsistent with the remainder of the statute's text and structure and unsupported by

even "*a single cogent reason.*" Pet. App. 62a (emphasis in original).

In sum, *certiorari* is unwarranted by any measure. This case is both moot and interlocutory; there is no circuit split; and the decision below is plainly correct. The Petition should be denied.

OPINIONS BELOW

The D.C. Circuit's unreported *per curiam* disposition is reprinted at Pet. App. 1a-3a. The district court's opinion is reported at 700 F. Supp. 2d 138 (D.D.C. 2010) and reprinted at Pet. App. 4a-11a. The Food and Drug Administration's unreported Letter Decision is reprinted at Pet. App. 12a-30a.

Neither FDA nor Apotex timely petitioned this Court for review of the D.C. Circuit's related decision in *Teva Pharmaceuticals USA, Inc. v. Sebelius*, which is reported at 595 F.3d 1303 (2010). Nonetheless, much of Apotex's Petition addresses the merits of that decision, which is reprinted at Pet. App. 31a-71a. The underlying district court decision in that case is reported at 638 F. Supp. 2d 42 (D.D.C. 2009) and reprinted at Pet. App. 72a-106a.

JURISDICTION

The D.C. Circuit's judgment was entered on July 6, 2010, and Petitioner has invoked this Court's jurisdiction under 28 U.S.C. § 1354(1). As set forth below, however, the Petition does not present a live case or controversy, and this Court accordingly lacks Article III jurisdiction to reach the merits. *See* U.S. CONST. art. III.

PERTINENT STATUTORY AND CONSTITUTIONAL PROVISIONS

Petitioner's Appendix includes some—but not all—of the pertinent statutory provisions. The remainder are set forth at Resp. App. 1a-6a.

STATEMENT OF THE CASE

A. The Hatch-Waxman Framework

As modified by the Medicare Modernization Act ("MMA"), the Hatch-Waxman Act establishes the procedure for obtaining new drug approvals in the United States. 21 U.S.C. § 355 *et seq.* It requires the manufacturer of a proposed brand-name drug to complete a New Drug Application ("NDA") that contains clinical data showing the proposed drug's safety and efficacy, *id.* § 355(b)(1), as well as information regarding each patent the applicant asserts as claiming the proposed drug (including its scheduled expiration date), *id.* § 355(b)(2); 21 C.F.R. § 314.50(h); *id.* § 314.53(b).

Generic drugs contain the same active ingredients and provide the same benefits as their brand-name counterparts, but typically are less expensive. Before Hatch-Waxman, generic companies had to complete a full NDA to obtain FDA approval; that requirement almost invariably made generic market entry cost-prohibitive. In 1984, Congress enacted Hatch-Waxman to remove that barrier, increase the availability of generics, and reduce drug costs. *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

To that end, Hatch-Waxman authorizes FDA to approve a generic drug if the generic applicant can

demonstrate its product's bioequivalence to a "listed" (or previously approved) brand-name drug. Generic applicants do so by submitting an Abbreviated NDA ("ANDA") that includes studies demonstrating bioequivalence. 21 U.S.C. § 355(j). If FDA accepts those studies, the generic applicant need not replicate the brand manufacturer's clinical studies. *Id.* § 355(j)(2)(A); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

The statute also requires each ANDA to include a "certification" to each patent the brand manufacturer identified as claiming the brand-name drug. *Id.* § 355(j)(2)(A)(vii). To make this system work, FDA must "publish" the patent information it receives from brand companies. *Id.* § 355(j)(7)(A). FDA's official patent list is known as "the Orange Book." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004).

Generic applicants consult that list and then make one of four certifications: (1) that no patent information was filed for the brand-name drug ("Paragraph I certification"); (2) that a listed patent "has expired" ("Paragraph II certification"); (3) that the generic drug will not be marketed until "the date on which [a listed] patent will expire" ("Paragraph III certification"); or (4) that a listed patent is invalid, unenforceable, and/or will not be infringed by the proposed generic drug ("Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

Paragraph IV certifications are critically important. They typically signal the generic's intent to sell its products before the scheduled expiration of a listed patent and thereby provide consumers with expedited price relief. *Teva Pharms. USA, Inc. v.*

Leavitt ("*Teva v. Leavitt*"), 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier.").

But filing such certifications is risky. The first Paragraph IV challenger bears significant research-and-development and legal costs to design around and/or contest the validity of a listed patent. And if those efforts succeed, merely filing such a certification is an act of infringement that could result in years of costly patent litigation. *See* 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

To encourage generics to accept those risks, the statute rewards the first patent challenger with a 180-day period of marketing exclusivity during which no other generic version of the drug may be sold. *See, e.g.*, *Teva v. Leavitt*, 548 F.3d at 104 ("Marketing exclusivity is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation.").

Pursuant to the MMA, the first patent challenger can "forfeit" its exclusivity in certain circumstances. 21 U.S.C. § 355(j)(5)(D)(i). Two such circumstances are relevant here. First, the first generic applicant can forfeit exclusivity if it fails promptly to market its products after certain events—including (in general terms) a successful outcome in patent litigation, or after the brand manufacturer withdraws (or "delists") a patent from the Orange Book. *Id.* § 355(j)(5)(D)(i)(I). These provisions are known as the "failure-to-market" forfeiture trigger.

Second, the first applicant may forfeit exclusivity if "[a]ll of the patents as to which the applicant submitted a [Paragraph IV certification] have expired." *Id.* § 355(j)(5)(D)(i)(VI). This provision codified FDA's longstanding practice of rejecting exclusivity where the first applicant failed to begin selling its products before the challenged patent expired *naturally—i.e.*, at the end of its scheduled term. *See Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003).

B. The Delisting Rule

Shortly after Congress passed Hatch-Waxman, brand companies realized that delisting a challenged patent could eliminate exclusivity and thereby undercut the incentive for generic applicants to challenge patents over the long-run. That was so because generic applicants can certify *only* to patents listed in the Orange Book, and can receive exclusivity *only* if they maintain a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv) (2002); *id.* § 355(j)(5)(B)(iv)(II)(bb) (2003). FDA acquiesced in this practice, and given the ease with which brand manufacturers thus could eviscerate the incentive for challenging their patents, FDA's approach to delisting substantially reduced the motivation for generic applicants to develop and file early patent challenges.

Teva eventually sued FDA, and the D.C. Circuit rejected the Agency's acquiescence in this manipulative practice at *Chevron* step one. *Ranbaxy*, 469 F.3d at 126. As *Ranbaxy* explained, FDA's delisting policy gutted the exclusivity reward by allowing brand companies to "reduce[] the certainty of receiving a period of marketing

exclusivity," and thereby "diminish[ed] the incentive for [generics] . . . to challenge a [listed] patent." *Id.* at 126. In sum, the Court held, "FDA may not . . . change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Id.* (quoting *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994)).

Ranbaxy, however, was decided before the MMA. And seizing upon the MMA's new "failure-to-market" forfeiture clause—which in certain circumstances provides for forfeiture after a delisting, 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)—FDA held that *Ranbaxy* did not survive the MMA. Pet. App. 36a. Instead, according to FDA, "[b]rand manufacturers are ... free to delist challenged patents *whenever* they please—and any such delisting [causes a forfeiture]." *Id.* at 58a (emphasis added). This approach was known as the "Delisting Rule."

C. Losartan Potassium Products

Losartan potassium is an antihypertensive agent. Merck holds two NDAs for the losartan potassium products Cozaar® and Hyzaar®. When those drugs were approved, Merck listed the same three patents[1] in the Orange Book for both: U.S. Patent No. 5,138,069 ("the '069 patent"), which was scheduled to block competition through February 11, 2010; U.S.

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[1] Merck also listed a fourth patent for Cozaar®, but that patent relates to a treatment for which Teva did not seek approval and thus posed no barrier to the approval of Teva's ANDA.

Patent No. 5,153,197 ("the '197 patent"), which was scheduled to block competition through April 6, 2010; and U.S. Patent No. 5,608,075 ("the '075 patent"), which was scheduled to block competition through September 4, 2014.[2]

On December 18, 2003, Teva submitted its generic Cozaar® ANDA. Teva's ANDA contained Paragraph III certifications to the '069 and '197 patents, meaning that it would not market its products until the '197 patent's scheduled expiration in April 2010. However, Teva also submitted a Paragraph IV certification to the '075 patent, claiming that that patent is invalid, unenforceable, and/or would not be infringed by Teva's products—and thus that Teva intended to begin marketing its products years before that patent's scheduled expiration in 2014. Teva was the first generic applicant to challenge the '075 patent. Pet. App. 40a.

On May 24, 2004, Teva submitted its generic Hyzaar® ANDA. That ANDA contained the same patent certifications as Teva's Cozaar® ANDA—including a Paragraph IV certification to the '075 patent. Once again, Teva was the first generic Hyzaar® applicant to challenge the '075 patent. *Id.*

As the first Paragraph IV filer, Teva became eligible for 180-day exclusivity for both drugs. *Id.* Teva then notified Merck of its certifications, explaining that most of the '075 patent's claims were

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[2] Each patent actually was scheduled to expire before these dates. However, Merck received a period of "pediatric exclusivity" which prevented FDA from approving ANDAs until six months after each patent expired. 21 U.S.C. § 355a.

invalid based on prior art and that Teva's products would not infringe the patent's remaining claims under the doctrine of equivalents. Merck, however, did not sue Teva. *Id.* Instead, in March 2005—*after* Teva submitted its exclusivity-qualifying Paragraph IV certifications to the '075 patent—"Merck asked the FDA to delist the '075 patent, which the agency did." *Id.* Then, *after* asking FDA to delist the '075 patent, Merck apparently stopped paying "maintenance fees" on the now-worthless patent. *Id.* at 6a.

By doing so, Merck effectively conceded that Teva's Paragraph IV challenge was so strong that Merck could not reasonably assert that patent against any generic applicant. Teva thus achieved precisely what Congress sought to reward with exclusivity: It identified a competition-blocking patent, invested the resources needed to challenge it, and successfully removed it as a barrier to competition—thereby opening the market to generic entry more than four years earlier than would have been possible without Teva's challenge. Under FDA's Delisting Rule, however, "Teva had by the fall of 2008 *already* forfeited" its exclusivity because of Merck's unilateral decision to delist the '075 patent. *Id.* at 41a (emphasis original).

D. The *Teva* Litigation

In June 2009, Teva sued FDA to protect its 180-day exclusivity period, arguing that the Delisting Rule was arbitrary, capricious, and inconsistent with the statute. The district court (Collyer, J.) ultimately consolidated Teva's initial request for preliminary injunctive relief with a trial on the merits, and entered judgment for FDA. *Id.* at 33a.

Teva appealed, and the D.C. Circuit (per Williams, J.) reversed on March 2, 2010. *Id.* at 66a. Paying close attention to the statute's text and structure, Judge Williams's opinion for the court held there was "no reason to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity." *Id.* at 63a; *see also id.* at 62a ("The agency ... *offers not a single cogent reason* why Congress might have ... provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity.") (emphasis original).

The D.C. Circuit then remanded the case for the entry of appropriate relief, *id.* at 66a, but simultaneously entered a routine order withholding its mandate until seven days after FDA's deadline for seeking rehearing.

E. Post-Judgment Proceedings

That routine order would have prevented the district court from entering relief on remand *before* FDA could have approved other applicants on April 6. So on March 9, Teva moved the D.C. Circuit to issue its mandate forthwith. Emer. Mot. To Issue Mandate (Mar. 9, 2010).

That same day, however, Apotex apparently informed FDA that Merck's '075 patent may have prematurely expired *in March 2009* due to Merck's unilateral failure to pay maintenance fees. FDA then opposed Teva's motion for immediate issuance of the mandate, asserting (like Apotex here) that Merck's decision to halt maintenance fee payments meant that "a forfeiture event other than the delisting of the '075 patent—namely, expiration of a patent that is the subject of a paragraph IV

certification[—]has, in fact, occurred." FDA Opp. to Emer. Mot. To Issue Mandate at 7 (Mar. 11, 2010).

Teva promptly replied, explaining that FDA's effort to divorce Merck's unlawful delisting request from its failure to pay maintenance fees

> boils down to the absurd proposition that brand manufacturers somehow are allowed to achieve through the back door (by not paying maintenance fees on a challenged patent) precisely what th[e D.C. Circuit]'s decisions in both this case and *Ranbaxy* forbid them from doing through the front door (by delisting the challenged patent in the first place). As [*Teva*] recognized, however, there is 'not a single cogent reason why Congress might have permitted ... a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity,' and that judgment is controlling here.

Reply in Supp. of Emer. Mot. at 11 (Mar. 12, 2010) (quoting Pet. App. 62a). After considering the parties' submissions, the D.C. Circuit granted Teva's motion and issued its mandate on March 12.[3]

F. Post-Remand Proceedings

On remand, the district court directed FDA to promptly file an administrative decision addressing the potential impact of Merck's conduct on Teva's eligibility for exclusivity, and suggested that any challenge to that decision could be raised "in a new

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[3] FDA later petitioned for rehearing *en banc*, but the D.C. Circuit unanimously denied the petition on May 17.

lawsuit." Order Amending Judgment at 3 n.4 (D.D.C. Mar. 26, 2010).

On March 26, FDA then issued the Letter Decision giving rise to this litigation. Pet. App. 12a-30a. Although the Agency took issue with the D.C. Circuit's delisting opinion, it nonetheless held that the appellate court's reasoning "preclude[s] a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder." *Id.* at 28a (discussing *id.* at 62a). It therefore declared that FDA "will not approve any other [losartan] ANDA until [Teva] has received approval of its ANDA, begun commercial marketing, and the 180-day exclusivity period has expired." *Id.* at 29a.

Apotex then filed a new lawsuit, seeking a TRO and preliminary injunction that together would bar FDA from awarding Teva exclusivity and compel the Agency to approve Apotex's ANDA immediately. On April 2, the district court denied the motion. *Id.* at 11a. With respect to Apotex's likelihood of success, the district court held that FDA properly "applied the reasoning of the Circuit to a different but, on these facts, closely related question." *Id.* at 9a. And on the equities, the court held that Apotex's purely economic injuries did not constitute irreparable harm, *id.* at 10a; that the requested relief "would certainly injure Teva," *id.*; and that the public interest weighed against relief given the exclusivity reward's "'pro-consumer'" goals. *Id.* at 10a-11a (quoting *id.* at 64a).

On April 5, Apotex asked the D.C. Circuit to stay all generic losartan approvals and summarily reverse the district court's decision. The D.C. Circuit

promptly denied those motions, and FDA approved Teva's ANDAs on April 6. Teva began selling its products that evening, thereby triggering its 180-day exclusivity period.

On July 6, another D.C. Circuit panel (Tatel, Griffith, Kavanaugh, JJ.) affirmed the district court's denial of Apotex's preliminary injunction request in an unpublished *per curiam* order. Pet. App. 1a-3a. That summary disposition explained that once "the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent ... to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute." *Id.* at 2a-3a.

Teva's 180-day period of exclusivity ended on October 3. The next day, Apotex filed its Petition. Apotex received approval to market its generic losartan potassium products on October 6, and apparently has been selling its products ever since.[4]

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[4] *See* FDA, *Drugs @ FDA: FDA Approved Drug Products*, *at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Set_Current_Drug&ApplNo=090790&DrugName=LOSARTAN%20POTASSIUM&ActiveIngred=LOSARTAN%20POTASSIUM&SponsorApplicant=APOTEX%20CORP&ProductMktStatus=1 (last visited Dec. 9, 2010).

REASONS FOR DENYING THE WRIT

I. This Case Is Moot.

Apotex's complaint—and the preliminary injunction motion addressed by the sole D.C. Circuit decision at issue here, Pet. App. 2a-3a—sought only prospective relief challenging Teva's entitlement to 180-day marketing exclusivity. But Teva's 180 days of exclusivity have come and gone, and while this Court can do many things, it can't turn back time. There is thus no case or controversy left for the Court to resolve; any opinion regarding the merits would be purely advisory.

Nor does this case present one of those "exceptional situations" involving an issue that is "capable of repetition while evading review." *Alvarez v. Smith*, 130 S. Ct. 576, 581 (2009) (internal citations and quotations omitted). Though Apotex has identified a handful exclusivity-grounding patents that the brand manufacturer deliberately let lapse, there is no reason why the question it seeks to raise here will evade review if, as Apotex speculates, it ever arises again. After all, challenges to the legal rules FDA applies in making exclusivity decisions can be brought well before an exclusivity period is scheduled to begin—and with ample time for this Court to review the issue Apotex seeks to raise in a case where it actually matters.

A. This Case Was Moot Even Before Apotex Filed Its Petition.

It is black-letter law that "a case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Powell v. McCormack*, 395 U.S. 486, 496 (1969).

Accordingly, a given case or controversy not only must be "live" at the outset of litigation; it must remain so "'through all stages of federal judicial proceedings, trial and appellate.'" *Spencer v. Kemna*, 523 U.S. 1, 7 (1998) (quoting *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477-478 (1990)).

Apotex's lawsuit, however, was moot even before the Petition was filed. This case involved a single 180-day period of marketing exclusivity that began on April 6 and ended at midnight on October 3. Apotex is now selling its products, unhindered by the exclusivity period it sought to challenge. Any interest Apotex had when it filed suit long ago ceased to exist; nothing this Court can do would give Apotex relief. Accordingly, the Petition should be denied. *See Lewis*, 494 U.S. at 480 ("Where on the face of the record it appears that the only concrete interest in the controversy has terminated, reasonable caution is needed to be sure that mooted litigation is not pressed forward, and unnecessary judicial pronouncements ... obtained."); *see also Bunting v. Mellen*, 541 U.S. 1019, 1021 (2004) (Stevens, Breyer, and Ginsburg, JJ., respecting the denial of certiorari) (explaining that *certiorari* is properly denied where "there no longer is a live controversy").

B. This Issue Will Not Evade Review.

Nonetheless, Apotex half-heartedly suggests that this case falls within the "capable of repetition, yet evading review" exception to mootness. *See* Pet. 17 n.8. But that bald assertion is incorrect: There is no reason to assume that future cases raising this issue cannot be filed with "ample time to obtain judicial review." *Lewis*, 494 U.S. at 482.

That is so, as the D.C. Circuit's original delisting decision made clear, because there is no bar to pre-enforcement review of exclusivity issues. Given that the issues presented in such cases are "purely legal" and implicate a cognizable "hardship," Pet. App. 43a, 46a, courts "routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." *Id.* at 48a (citations omitted).

That, of course, explains why Apotex does not even try to argue that subsequent cases cannot be filed with sufficient lead-time to permit full judicial review. All a subsequent applicant would have to do is file a declaratory judgment action next time it faces an allegedly unlawful exclusivity period—and if Apotex is to be believed, there are 27 possible cases in which one might do so, *see* Pet. 25 (though that considerably overstates the number of cases in which the actual merits issue embedded in this preliminary injunction appeal might arise, *see infra* at III.B.).

In any event, this Court need "not decide in the first instance" whether an exception to the mootness doctrine applies. *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 168-169 (2004) (internal citation and quotations omitted). As explained below, this case remains pending before the district court—which can and should resolve the mootness issue (by making any necessary findings that bear on that inquiry) in the first instance. *See, e.g., United States v. Brandau*, 578 F.3d 1064, 1065 (9th Cir. 2009); *Pakootas v. Teck Cominco Metals, Ltd.*, 452 F.3d 1066, 1071 n.10 (9th Cir. 2006); *Tandy v. City of Wichita*, 380 F.3d 1277, 1291 (10th Cir. 2004).

II. The Petition Arises In The Interlocutory Context Of A Preliminary Injunction Proceeding.

Even if this case were not moot, it would be a poor vehicle to address the question it purports to present, because it arises in the interlocutory context of a preliminary injunction proceeding. Again, the D.C. Circuit merely affirmed the district court's denial of Apotex's motion for interim relief, and the case remains pending below.

This Court typically does not exercise its discretionary jurisdiction over interlocutory appeals, and petitions arising from preliminary injunction proceedings are particularly ill-suited for review. After all, the legal issues embedded in such petitions are not squarely presented: The question on appeal from the denial of a preliminary injunction is *not* whether the lower courts properly resolved the merits, but whether the court abused its discretion by denying interim relief. While that inquiry turns in part on a tentative assessment of the merits, it also requires the movant to demonstrate a likelihood of irreparable injury absent immediate relief. Here, of course, Apotex cannot possibly demonstrate such an injury because Teva's exclusivity period is over—and the D.C. Circuit's decision thus would have to be affirmed without respect to the merits.

A. There Has Been No Final Judgment.

As set forth above, no final judgment has been entered in this case. That fact alone is fatal to the Petition, because this Court's settled practice is to "await final judgment in the lower courts before exercising ... certiorari jurisdiction." *VMI v. United States*, 508 U.S. 946, 946 (1993) (Scalia, J.,

respecting the denial of certiorari) (citing *American Constr. Co. v. Jacksonville, T. & K.W.R. Co.*, 148 U.S. 372, 384 (1893); *Locomotive Firemen v. Bangor & Aroostook R. Co.*, 389 U.S. 327, 328 (1967) (per curiam); R. Stern, E. Gressman, & S. Shapiro, SUPREME COURT PRACTICE § 4.18, pp. 224-226 (6th ed. 1986)).

That approach controls here, where the *only* decision before this Court is the D.C. Circuit's unpublished order affirming the district court's denial of Apotex's preliminary injunction motion. Pet. App. 2a-3a. The legal merits remain pending before the district court on remand. And while one might think there is little left for the district court to resolve given that Teva's exclusivity period now has ended, Apotex continues to resist the entry of a final judgment; indeed, Apotex won't even commit to dismissing its lawsuit in the event this Court denies *certiorari*. *See* Resp. App. 8a ("Should the petition not be granted, Apotex will then *consider* whether to dismiss the case ....") (emphasis added).

The Petition thus should be denied. While Teva has no idea what Apotex intends to do at the district court, this Court's review can surely await the entry of judgment after Apotex decides it has finished litigating the merits of its case.

B. The Legal Issue Apotex Seeks To Raise Is Not Squarely Presented.

The fact that this Petition arises from the denial of a preliminary injunction provides an additional basis for denying review. While Apotex purports to raise the purely legal question of whether the D.C. Circuit properly interpreted the Hatch-Waxman Act, *see* Pet. i, that question isn't actually presented.

Instead, the only question before this Court is whether the district court abused its discretion when it applied the four-factor preliminary injunction test to deny Apotex's motion. *See Winter*, 129 S. Ct. at 374; *Munaf v. Geren*, 553 U.S. 674, 690-91 (2008).

Yet for all the ink it spills on the underlying merits, Apotex doesn't say a word about the preliminary injunction standard—and for good reason. As the district court recognized, Pet. App. 8a-9a, that standard requires Apotex to demonstrate, among other things, both a likelihood of success on the merits *and* a likelihood of irreparable injury in the absence of immediate equitable relief. *Winter*, 129 S. Ct. at 374-75.

Apotex cannot satisfy either requirement. On one hand, the fact that Apotex's sole legal claim is moot forecloses any possibility that Apotex could demonstrate a likelihood of success. On the other hand, Apotex does not contest the district court's factual finding that the company would not suffer irreparable injury absent injunctive relief. Pet. App. 10a (citing *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam); *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001)). And Apotex certainly cannot demonstrate such an injury now: Teva's exclusivity period is over, and Apotex is on the market. There is thus nothing left to enjoin, and no need for this Court to reach the merits. The case would have to be affirmed based solely on the equities. *See, e.g.*, *Winter*, 129 S. Ct. at 374-76 (conditioning injunctive relief on proof that irreparable injury is "likely," and denying such relief without addressing the merits

based on "[a] proper consideration of the[equitable] factors *alone*") (emphasis added).

III. There Is No Circuit Split, And Apotex Exaggerates the Likelihood That The Embedded Merits Issue Will Recur.

Separate and apart from those grounds for denying the Petition, there is no circuit split on the issue Apotex purports to raise, and Apotex in any event exaggerates the likelihood that it will recur.

A. There Is No Circuit Split.

Apotex concedes that the D.C. Circuit is the only appellate court that has addressed whether the Hatch-Waxman Act allows brand manufacturers to deprive generic applicants of 180-day exclusivity by ceasing to pay maintenance fees on Orange Book-listed patents. Pet. 26. And the appellate court's decision on this point is both fully consistent with two prior D.C. Circuit cases, *see* Pet. App. 31a-71a; *Ranbaxy*, 469 F.3d at 126, and uncontested by any other circuit court.

Despite this uniformity, Apotex claims that *certiorari* is appropriate because it believes a circuit split is unlikely to develop. *See* Pet. 26-27. That is so, Apotex asserts, because "the D.C. Circuit is the usual forum for these disputes." *Id.* at 26 (internal quotation omitted).

Unlike many federal agencies, however, FDA is not subject to exclusive suit in the D.C. Circuit. And despite Apotex's best efforts to obscure the record, lawsuits regarding FDA's interpretation of the Hatch-Waxman Act (including its 180-day exclusivity provisions) commonly *are* filed outside Washington D.C. Indeed, these out-of-circuit cases include some

of the most significant Hatch-Waxman cases that have ever been litigated. *See, e.g.*, *Mylan Pharms., Inc. v. FDA*, 454 F.3d 270 (4th Cir. 2006) (180-day exclusivity); *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003) (Orange Book patent listings); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (same); *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001) (Orange Book patent listings); *Granutec, Inc. v. Shalala*, Nos. 97-1873, 97-1874, 1998 WL 153410 (4th Cir. Apr. 3, 1998) (180-day exclusivity); *Schering Corp. v. FDA*, 51 F.3d 390 (3d Cir. 1995) (generic approval requirements); *Dr. Reddy's Labs.*, 302 F. Supp. 2d at 340 (180-day exclusivity); *Mylan Pharms., Inc. v. Thompson*, 207 F. Supp. 2d 476 (N.D. W.Va. 2001) (180-day exclusivity).

That perhaps explains why FDA itself is preparing to litigate these issues in other jurisdictions. Indeed, as the Agency's senior Hatch-Waxman counsel recently explained, FDA expects that the issues addressed in the losartan cases are "likely to arise again soon *in other courts*." Resp. App. 11a (emphasis added). There is thus no basis for Apotex's attempt to rule out the possibility of a future circuit split.

Faced with these facts, Apotex ultimately resorts to speculation. It hypothesizes that future first applicants might be able to channel all 180-day exclusivity cases to the D.C. courts before subsequent applicants are "able to bring suit elsewhere." Pet. 27. But without belaboring the point, such admittedly creative conjecture—which even Apotex concedes rests on an "unclear" premise, *id.*—hardly provides a basis for granting *certiorari*.

B. Apotex Exaggerates The Likelihood That The Embedded Merits Issue Will Recur.

Of course, the absence of a circuit split does not automatically preclude review; this Court sometimes takes cases that present particularly important issues which are likely to recur. Apotex thus tries to shoehorn its Petition into this narrow class of cases, asserting that "billions of dollars" are at stake because "[m]any more [cases] are coming down the pike." Pet. 24-25. Indeed, Apotex argues, it has identified "27 patents for brand-name drugs ... for which ... the challenged patent has been delisted *or* allowed to expire." *Id.* at 25 (emphasis added).

That not only overstates the case; it highlights yet another problem with the Petition. Despite Apotex's best efforts to challenge the D.C. Circuit's original delisting decision (Pet. App. 31a-71a), this Petition does *not* arise from Teva's lawsuit challenging the FDA's Delisting Rule, and the decision in that case is *not* before the Court. Instead, this case arises from Apotex's subsequent—*separate*—lawsuit challenging FDA's application of the patent-expiry forfeiture trigger, and that's the only merits issue addressed in the appellate court's preliminary injunction decision, Pet. App. 2a-3a.

That matters, because as Apotex noted in the district court (but tellingly declines to mention here), *only four* of the "27 patents" it claims to be at issue involve alleged patent expiry—*and one of those is the losartan patent at issue in this case.* *See* Apotex Reply to Opp. to Mot. for Prelim. Inj. at 8 & n.3 (D.D.C. Apr. 1, 2010). Thus, contrary to Apotex's suggestion that another 27 cases are likely to raise

the issue addressed by the appellate court, just 3 other cases implicate this issue—*and one of them appears to arise under the pre-MMA statute* (and so would not be controlled by a decision in this case). Neither of the remaining two cases involves a "blockbuster" drug, *cf.* Pet. 25, and even if they did, the prospect that two future cases may (or, depending on their unique facts, may not) give rise to similar litigation is far too thin a reed on which to ground *certiorari*.

IV. The D.C. Circuit's Preliminary Analysis Of The Merits Was Correct.

Finally, there is no need for this Court's review because the appellate court's preliminary analysis of the merits was correct. As three different panels of the D.C. Circuit now have recognized, it upends both law and logic to think that Congress created an elaborate incentive scheme designed to encourage generic companies to challenge dubious brand-name patents, but simultaneously empowered the brand companies who assert those dubious patents to eviscerate that incentive scheme. *Ranbaxy*, 469 F.3d at 126; Pet. App. 64a-66a; Pet. App. 2a-3a. In short, because Apotex's interpretation of the statute would allow brand companies to manipulate the exclusivity incentive despite the absence of *any* suggestion in the text, history, or structure of the statute that Congress intended to give brand companies that power, the D.C. Circuit properly held that Apotex was unlikely to prevail on the merits. Pet. App. 2a.

A. The MMA Did Not Abrogate *Ranbaxy*'s Holding On Delisting.

Long before this case arose, the D.C. Circuit held that the plain text and structure of the Hatch-

Waxman Act precluded FDA's policy of acquiescing in a brand manufacturer's unilateral request to delist a patent from the Orange Book following the submission of an exclusivity-qualifying Paragraph IV certification. As then-Chief Judge Ginsburg's opinion in *Ranbaxy* explained, "FDA's policy allows an NDA holder [to] diminish[] the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book.... FDA may not, however, change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Ranbaxy*, 469 F.3d at 126 (quoting *MCI*, 512 U.S. at 231 n.4).

Apotex did not challenge that holding in either the original delisting case or its follow-on case regarding patent expiry. And apart from a stray footnote that would not be sufficient to raise the issue here even if it were not waived below, Pet. 26 n.11, Apotex does not seriously contest that holding now. Accordingly, as the D.C. Circuit recognized in its original delisting decision, "[t]he real issue" is whether the MMA "altered the statute's incentive structure to the point that *Ranbaxy*'s reasoning no longer controls ...." Pet. App. 60a.

Apotex contends that that's precisely what the MMA did, and points to the statute's new "forfeiture triggers" for support. Pet. 29-32. Indeed, Apotex claims that "[t]he D.C. Circuit gave no meaningful consideration to that text." *Id.* at 29; *see also id.* at 30 ("[T]he D.C. Circuit ... ignored those clear textual commands ...."). The court did no such thing.

To the contrary, its original delisting decision began by addressing the MMA's failure-to-market forfeiture trigger head-on—and carefully explained that the text of each of its subsections requires some action by the generic applicant before it kicks in:

> Setting aside the subsection at issue in this case—[the delisting forfeiture trigger] codified as (bb)(CC)—the "failure to market" forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter. No forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters an unfavorable settlement agreement. The latter necessarily entails some participation by the generic; the former invariably involves significant expense for the brand manufacturer, and affords the victorious generic the opportunity to ask the court to delay entering final judgment until a date that would not trigger forfeiture prematurely.

Pet. App. 61a-62a (discussing 21 U.S.C. § 355(j)(5)(D)(i)(I)).

Apotex nonetheless claims that the delisting forfeiture trigger is different than the provisions to which it is connected: "The MMA specifically identified patent delisting as a 'forfeiture event' and gave no indication that it would not apply if that delisting was the result of 'unilateral' action by the brand-name manufacturer." Pet. 29. But the appellate court carefully considered—and quite

properly rejected—that argument as well. As Judge Williams explained, that trigger does apply *if* "the patent targeted in a paragraph-IV filing 'is withdrawn by the' brand manufacturer." Pet. App. 62a (quoting 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)). But that language says nothing about *when* brand manufacturers are permitted to withdraw challenged patents. As the appellate court then explained, *another* provision of the statute helps answer that question, and it makes clear that the delisting trigger—just like the forfeiture provisions to which it is linked—also requires action by the generic applicant before it can be activated. *Id.* (discussing 21 U.S.C. § 355(j)(5)(C)(ii)(I).

That key statutory provision, which Apotex inexplicably omits from its statutory appendix, is known as the "delisting counterclaim," and it was enacted at the same time Congress added the delisting forfeiture trigger. *See id.* at 57a & n.4. As the appellate court explained, "[t]he [MMA] introduced a new procedure, a counterclaim in the brand manufacturer's patent infringement suit, *through which generic companies can force brand companies to delist an improperly asserted patent.* This counterclaim provision is *the only* portion of the statute that explicitly provides for the delisting of a patent after it has been challenged in an ANDA." *Id.* at 57a (emphases added; citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)).

And reading the delisting forfeiture trigger *in pari materia* with the delisting counterclaim provision, *see Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972)); construing the language of the delisting forfeiture trigger in the context of the other

failure-to-market forfeiture provisions, *see Gutierrez v. Ada*, 528 U.S. 250, 255, (2000) ("[W]ords ... are known by their companions."); and interpreting these provisions in light of "the whole statutory text, considering the purpose and context of the statute," *Dolan v. USPS*, 546 U.S. 481, 486 (2006), the appellate court explained that there is "*not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, *outside the counterclaim scenario identified by Teva*." Pet. App. 62a (second emphasis added).

Given the D.C. Circuit's meticulous analysis of the Act's interwoven text and structure, it is unclear how Apotex possibly can assert that the appellate court "gave no meaningful consideration to" the statute's language. Pet. 29. And with all due respect to Apotex, it is not Judge Williams's analysis of the statute that "wholly misses the point." Pet. 30. It is Petitioner's.

B. The D.C. Circuit Properly Resolved The Patent Expiry Issue.

Against this backdrop, it is easy to see why Judges Tatel, Griffith, and Kavanaugh concluded that Apotex's patent-expiry arguments warranted no more than a two-page *per curiam* disposition. Pet. App. 2a-3a. As FDA itself had concluded, Pet. App. 28a, the D.C. Circuit's prior decision in the delisting case foreclosed Apotex's claim: If brand companies cannot "'unilaterally' deprive the generic applicant of its exclusivity [by] delisting" a challenged patent, they cannot "'unilaterally' deprive the generic applicant of its exclusivity" through the simple artifice of ceasing to pay maintenance fees on such a

patent. *Id.* at 27a-28a (quoting *id.* at 35a, 63a; discussing 21 U.S.C. § 355(j)(5)(D)(i)(VI)).

Any other outcome would be absurd. It would allow brand manufacturers to do through the back door (not paying maintenance fees) precisely what the statute bars them from doing through the front door (delisting a patent), despite the lack of "*a single cogent reason* why Congress might have permitted brand manufacturers [to] unilaterally deprive the generic of its exclusivity." *Id.* at 62a (emphasis original). FDA thus did not remotely err by reading the patent expiry forfeiture trigger in the context of the broader statute and pertinent caselaw. As the appellate court explained, when "viewed in the context of the statute's incentive structure, it becomes clear that Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a [challenged] patent ... to strip the first generic applicant of the 180-day [exclusivity] period." Pet. App. 2a-3a (citing *id.* at 62a-64a); *see also Dolan*, 546 U.S. at 486 ("Interpretation of a word or phrase depends upon reading the whole statutory text, considering the purpose and context of the statute, *and consulting any precedents or authorities that inform the analysis.*") (emphasis added).

Indeed, wholly apart from its consistency with the D.C. Circuit's original decision on delisting, there are independent reasons for construing the patent-expiry trigger to prevent this sort of backdoor manipulation by brand manufacturers.

First, Hatch-Waxman's other references to patent expiration demonstrate that Congress was concerned only with *natural* patent expiration. In particular,

the statute requires Paragraph III certifications to state, at the time certification is filed, "the date on which [the listed] patent *will expire*." 21 U.S.C. § 355(j)(2)(A)(vii)(III) (emphasis added). But if brand manufacturers can cause listed patents to "expire" for Hatch-Waxman purposes by simply declining to pay maintenance fees, Paragraph III would be reduced to a guessing game: Because the brand manufacturer could quit paying those fees at *any* time, generic applicants could only speculate about what date to list. By contrast, the only date that can be stated with certainty is the date when the patent is scheduled to expire naturally, and as Paragraph III thus makes clear, that is the one that counts for purposes of the Hatch-Waxman Act.

Second, unlike patents that expire naturally, patents which "expire" for non-payment of maintenance fees don't actually die. Instead, they can be revived—in some cases "at any time"—and thereafter "shall be considered as not having expired" at all. 35 U.S.C. § 41(c)(1). There simply is no reason to think that Congress intended Hatch-Waxman exclusivity to turn on a technical form of patent expiry that may only be transient and fleeting. Indeed, that interpretation of the statute is doubly absurd. It not only would allow brand companies to *deliberately* strip the first generic's exclusivity, but would allow them to do so *negligently* as well. In particular, if the brand manufacturer inadvertently misses a fee payment and the first applicant is deemed to have forfeited exclusivity, FDA could approve all ANDAs immediately—leaving the first applicant without recourse if the patent later is revived and thus treated "as not having expired." *Id.* Congress could not possibly have

intended the patent-expiry trigger to produce such an absurdity.

Finally, the underlying rationale for divesting the first applicant of exclusivity based on patent expiration does not remotely apply where a brand manufacturer artificially pretermits a challenged patent's natural term. Long before the MMA was enacted, FDA interpreted the statute to preclude exclusivity after a patent's *natural* expiration. *See Dr. Reddy's*, 302 F. Supp. 2d at 354-55. The basis for that approach was simple. Paragraph IV challenges are designed to help expedite generic competition, *Teva v. Leavitt*, 548 F.3d at 106, but where the first applicant fails to launch before the challenged patent expires on its own, "there is no longer a need to provide an incentive to challenge it." *Dr. Reddy's*, 302 F. Supp. 2d at 354. In other words, where a Paragraph IV challenge accomplishes nothing, there is nothing to reward.

By contrast, where a patent lapses not by the mere passage of time, but rather (as here) because the first applicant's Paragraph IV certification *caused* the patentee to abandon its patent, the applicant's challenge has accomplished precisely what the statute rewards: It has opened the market to competition years earlier than would have been possible absent that challenge, and there is no reason to think that Congress intended to deprive generic applicants of their reward for achieving precisely what Paragraph IV challenges are designed to achieve.

Against this backdrop, it is clear that the patent-expiry trigger simply codified FDA's prior practice of stripping exclusivity following a patent's natural

expiration; there is no support in the text, structure, or history of the MMA for any other interpretation, as the D.C. Circuit's decision in this case recognized. Pet. App. 3a ("Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity.").

C. The D.C. Circuit's Decision Is Consistent With The Statute's Purposes.

Finally, Apotex asserts that awarding exclusivity under these circumstances harms consumers, and indeed that it only serves the brand manufacturer's interests. Pet. 32-34. Nothing could be further from the truth. As the D.C. Circuit repeatedly has explained, the Hatch-Waxman Act's 180-day exclusivity incentive exists to encourage generic companies to challenge bogus patents as quickly as possible; without that incentive, fewer patent challenges will be filed, and those that are filed will not be filed as fast. *E.g.*, Pet. App. 63a-64a.

Apotex does not deny that reality, but seeks to downplay it by asserting that "any discouraging effect such action might have on generic manufacturers would be, at best, indirect and delayed." Pet. 33. That assertion is at odds with the reality of this business. Like every other company, Teva has a limited budget—and every day it must make decisions about how to use its limited resources. So when the company is comparing two potential patent challenges head-to-head, a key question is which of those two opportunities is most

likely to yield exclusivity. After all, that reward "is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation." *Teva v. Leavitt*, 548 F.3d at 104. But if the company's analysis reveals that one of the patents at issue is held by a serial patent delister (as the record demonstrates to be the case here), the economics would change dramatically under Apotex's interpretation of the statute; as the D.C. Circuit long ago recognized, and with some understatement, "reducing the certainty of receiving a period of marketing exclusivity ... diminishes the incentive for a manufacturer of generic drugs to challenge a patent." *Ranbaxy*, 469 F.3d at 126.

Far from being "indirect and delayed," Pet. 33, the impact of Apotex's proposed interpretation would be felt every day, in virtually every ANDA filing decision—at least at any rational company. And make no mistake: Those consequences would have a significant adverse impact on the public's health and welfare over the long-run. As the D.C. Circuit once again explained in its original delisting decision:

> The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for

> generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.

Pet. App. 64a.

Teva thus earned its exclusivity here. It made enormous investments to both design around and mount a legal challenge to Merck's patent, all in the hopes of securing exclusivity and launching its products early. That effort resulted in a Paragraph IV certification so powerful that Merck simply gave up—first by delisting that patent, and then by ceasing to pay maintenance fees on a patent that Teva's Paragraph IV certification had rendered worthless.

Teva's Paragraph IV certification thereby cleared the path for generic competition to begin on these $1.5-billion-per-year drugs *four years earlier* than it would have if Teva had not challenged that patent—and thus will save consumers literally billions of dollars between April 6, 2010 (when Teva launched) and September 4, 2014 (when generics could have launched in the absence of a Paragraph IV challenge). There is no basis for thinking that Congress intended to let Merck punish Teva for delivering those savings to the public, and the D.C. Circuit thus properly affirmed the district court's decision denying Apotex's motion for preliminary injunctive relief.

CONCLUSION

For the foregoing reasons, the Petition should be denied.

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APPENDIX

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21 U.S.C. § 355(j)(5)(C)

(C) Civil action to obtain patent certainty.

(i) Declaratory judgment absent infringement action.

(I) In general. No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action. If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil

action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application. For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered

terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action.

(I) In general. If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages. An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

35 U.S.C. § 41(c)

(c)

(1) The Director may accept the payment of any maintenance fee required by subsection (b) of this section which is made within twenty-four months after the six-month grace period if the delay is shown to the satisfaction of the Director to have been unintentional, or at any time after the six-month grace period if the delay is shown to the satisfaction of the Director to have been unavoidable. The Director may require the payment of a surcharge as a condition of accepting payment of any maintenance fee after the six-month grace period. If the Director accepts payment of a maintenance fee after the six-month grace period, the patent shall be considered as not having expired at the end of the grace period.

(2) A patent, the term of which has been maintained as a result of the acceptance of a payment of a maintenance fee under this subsection, shall not abridge or affect the right of any person or that person's successors in business who made, purchased, offered to sell, or used anything protected by the patent within the United States, or imported anything protected by the patent into the United States after the 6-month grace period but prior to the acceptance of a maintenance fee under this subsection, to continue the use of, to offer for sale, or to sell to others to be used, offered for sale, or sold, the specific thing so made, purchased, offered for sale, used, or imported. The court before which such matter is in

question may provide for the continued manufacture, use, offer for sale, or sale of the thing made, purchased, offered for sale, or used within the United States, or imported into the United States, as specified, or for the manufacture, use, offer for sale, or sale in the United States of which substantial preparation was made after the 6-month grace period but before the acceptance of a maintenance fee under this subsection, and the court may also provide for the continued practice of any process that is practiced, or for the practice of which substantial preparation was made, after the 6-month grace period but before the acceptance of a maintenance fee under this subsection, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced after the 6-month grace period but before the acceptance of a maintenance fee under this subsection.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC.,

Plaintiff,

v.

KATHLEEN SEBELIUS *et al.*,

Defendants.

Case No. 1:10-cv-00517-RMC

RESPONSE OF APOTEX, INC. TO SHOW CAUSE ORDER

On September 27, 2010, this Court issued an Order requiring Apotex, Inc. ("Apotex") to show cause why this case should not be dismissed for failure to state a claim. Apotex respectfully requests that the Court continue to stay the proceedings in this case for an additional limited period of time in order to allow the Supreme Court to consider the petition for writ of certiorari filed by Apotex on October 4, 2010.

As this Court is aware, in this case Apotex challenged the Food and Drug Administration's ("FDA") determination that the decision in Teva v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010), precluded the forfeiture of exclusivity based on unilateral action by the brand-name manufacturer resulting in the expiration of a patent. This Court affirmed FDA's conclusion that Teva was entitled to

exclusivity for its ANDAs referencing Cozaar or Hyzaar. Apotex appealed and filed an emergency motion to stay the commencement of Teva's exclusivity period. The Court of Appeals for the District of Columbia denied Apotex's motion and, on July 6, 2010, issued a per curiam judgment affirming this Court's decision. The mandate was filed in this Court on September 2, 2010. On October 4, 2010, Apotex filed a petition for writ of certiorari in the Supreme Court from the decision of the Court of Appeals, docketed as Apotex, Inc. v. Kathleen Sebelius, et al., No. 10-453. A copy of the petition is attached. A response to the petition currently is due on November 4, 2010.

In the event the petition is granted, the Supreme Court would be expected to address the merits of FDA's interpretation of the Hatch-Waxman forfeiture provisions. Should the petition not be granted, Apotex will then consider whether to dismiss the case, thereby rendering further proceedings unnecessary. Apotex's counsel will notify the Court promptly of any action taken by the Supreme Court.

For these reasons, Apotex respectfully requests that the Court stay further proceedings in this case pending consideration of Apotex's petition for certiorari.

Date: October 18, 2010 Respectfully submitted

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FDA NEWS

Generic Line

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FDA Expects More Litigation Over Generic Exclusivity

A senior FDA attorney has admitted that Teva's successful challenge of the agency's policy for withdrawing a generic-drug maker's exclusivity period caught the FDA off-guard and predicted the issue is almost certain to come up again.

The case in question took place earlier this year when the U.S. Court of Appeals for the District of Columbia Circuit overturned FDA precedent and ruled that any unilateral action by a brand-drug maker, such as delisting a patent or letting it expire, cannot be used as a means for canceling a generic-drug maker's 180-day exclusivity period.

FDA Precedent

Teva had brought the case against the FDA in an attempt to stop the agency from withdrawing its exclusivity on generic versions of Merck's hypertension drugs Cozaar (losartan potassium) and Hyzaar (hydrochlorothiazide/losartan potassium) (*Generic Line*, March 17).

Prior to that ruling, the FDA had interpreted the Medicare Modernization Act (MMA), which contains the regulations for withdrawing an exclusivity period, as stating that patent delisting or expiration were valid reasons a generic-drug maker could lose its exclusivity.

While the agency said it disagreed with the appellate court's ruling, it nonetheless approved

Teva's exclusivity, saying the court's interpretation of the MMA gave it no choice (*Generic Line*, March 31).

Since that time, numerous companies have questioned the FDA about the decision and the agency feels it is likely to arise again soon in other courts, Elizabeth Dickinson, senior counsel in the FDA's Office of Chief Counsel, said this month at the Generic Pharmaceutical Association/FDA Fall Technical Conference in Bethesda, Md.

"The outcome of that case was something that surprised FDA," Dickinson said. "It severely constrained our decisionmaking on any exclusivity that appeared to be within the control of the innovator company."

The first place the issue may arise again could be the Supreme Court. Despite Teva's exclusivity on the drugs having already expired, generic-drug maker Apotex is appealing the case to the Supreme Court, saying that how exclusivity is awarded in all future cases is at stake (*Generic Line*, Oct. 13).

"If left undisturbed, the decision will benefit brand-name manufacturers, who want nothing more than to see a first applicant win exclusivity and thereby delay full-scale competition with multiple generic manufacturers," Apotex says in its petition for a writ of certiorari filed earlier this month. "It will also richly reward the generic manufacturer who wins a race to file a Paragraph IV certification but is unable promptly to bring the generic drug to market." — David Belian